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PATENT AND
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UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY
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In re Application of :
Partha S. Banerjee et al :
Serial No.: 09/887,281 : PETITION DECISION
Filed: June 22, 2001 :
Attorney Docket No.: 18025-1013 :

This is a decision on the petition under 37 CFR 1.144, filed July 22, 2002, requesting review of a restriction requirement under 35 U.S.C. 121.

BACKGROUND

A review of the file history shows that the examiner mailed a first Office action to applicants on January 30, 2002, setting forth a restriction requirement as follows:

> Group I, claims 1-61, 77-89 and 94-99, directed to a pharmaceutical formulation comprising formoterol;
> Group II, claims 62-67 and 90-93, directed to a kit comprising solutions and vials;
> Group III, claims 68-70 and 74-76, directed to a method of treatment of bronchial disorders; and
> Group IV, claims 71-76, directed to a packaged pharmaceutical composition.

The examiner reasoned that the inventions are independent and distinct because of different classification and separate subject matter and that each was capable of supporting its own patent.

Applicants replied to the restriction requirement on February 28, 2002, electing Group I with traverse and suggesting that some claims appeared in two groups and other claims were in the wrong group. Claims 62-64, 68-70, 74-76 and 90-91 were canceled. Applicants noted that claims 65-67 and 92-93 in Group II are not directed to kits, as identified by the examiner, suggesting that they should be included in Group I. Further argued was that the claims of Group I constituted a subcombination to the other Groups and is the invention on which all of the other groups depend for patentability.

The examiner mailed a new Office action to applicants on May 22, 2002. The examiner in responding to the traversal maintained the requirement without modification for reasons of record and as being non-persuasive, making the requirement Final.

Applicants filed this petition on July 22, 2002, presenting the same reasoning for traversal of the requirement as before in an expanded format.

DISCUSSION

Applicants argue that claims 65-67 and 92-93, placed in Group II to kits, are not directed to kits, but the combination of the pharmaceutical composition and a vial (a nominal container or packaging material). The claims do not identify the combination as a kit. It is further noted that claims 62-64 are directed to a kit which includes a nebulizer and are thus different from claims 65-67 and 92-93 which do not include a nebulizer. As such, applicants are correct in the placement of claims 65-67 and 92-93 in Group I. It is noted that the remaining claims of Group II and all claims of Group III have been canceled and no traversal with respect to the restriction requirement of these claims has been made.

Applicants traverse the restriction between Groups I and IV on the basis of combination/subcombination where the subcombination is required for patentability of the combination. As noted, Group I is directed to a pharmaceutical composition alone or in a vial. Group IV is directed to an article of manufacture comprising packaging material, a single dose of the pharmaceutical claimed and labeling material including treatment information. The packaging material is described only nominally (e.g.- it could be the vial of claims 65-67 or 92-93) as is the labeling material. Further, mere instructions for use or material identification on a label of a package contents are not patentable subject matter. Thus the only element on which patentability of the combination can be based is the pharmaceutical composition, *per se*. On review it is concluded that patentability of the combination is solely dependent on the elements of the subcombination. Therefor, restriction for examination purposes is not proper.

In summary, claims 1-61, 65-67, 71-73, 77-89 and 92-99 are considered to be directed to a single invention, a pharmaceutical composition alone or in a container (vial) or as a packaged and labeled medicament and constitute a single Group for restriction purposes.

DECISION

Applicants' petition under 37 CFR 1.144 is **GRANTED** for the reasons set forth. The examiner will examine all remaining pending claims as a single invention.

Applicants reply to the Office action was received August 22, 2002 and the application will be forwarded to the examiner for consideration thereof.

Should there be any questions with respect to this decision, please contact William R. Dixon, Jr., by mail addressed to: Director, Technology Center 1600, Washington, D.C. 20231, or by telephone at (703)308-3824 or by facsimile transmission at (703) 305-7230.

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